practice fusion™
Free, web-based Electronic Health Records

Therapy, Treatment Pattern & Outcomes

A proposal for:

Pharma Co. X

Prepared by:

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TABLE OF CONTENTS

PRACTICE FUSION™ | The fastest growing healthcare platform

One of Practice Fusion's main differentiators is our ability to intervene and message with both providers and their patients - before, during and after the patient visit enabling Practice Fusion to help implement and measure outcomes for multiple patient care interventions and programs. To learn more about various modules available within the EHR platform such as scheduling appointments, managing referrals, ordering and receiving lab/imaging results, e-prescribing and more: http://learn.practicefusion.com/

- Messaging from Practice Fusion to Providers
  - Provider educational materials, including clinical guidelines and best practices sent directly to providers through the PF EHR platform during the patient encounter
  - Clinical decision support integrated into the Practice Fusion EHR platform enabling physicians to enter critical patient metrics such as HbA1c labs and ejection fraction scores in a structured and searchable format within the patients electronic health record
  - Real-time alerts, drug safety or public health issues (e.g. flu widespread in your area, patient's chart does not include any documentation of an adult vaccination within the last five years, discuss availability and value of vaccination with patient)
- Messaging to Patients
  - Patient's recent lab results, prescription activity and refill reminders, educational materials that are disease specific are available to patient through their own personal, secure, online health record (Patient Fusion), as a follow up to their recent office visits with their physician
  - Notifying patients with chronic conditions (e.g. diabetes or cardiovascular disease) when it's time to schedule a follow up visit or refill an important medication as prescribed by their physician
- Data collection and messaging to Physicians can be used to supplement/enhance data that is routinely collected in the EHR
  - For providers, messaging can be at Point Of Care (POC) that is meaningful to the physician based on clinical guidelines and data for their patient as they are being seen
  - For patients through follow up care questions and responses, disease specific patient support programs and communications facilitated through the patient's personal health record (Patient Fusion)

Introduction

The Practice Fusion Data Science & Analytics (PF) team is pleased to present this proposal to Pharma Co. X to investigate chronic pain among patients with a new prescription for an extended release opioid (ERO) using EHR data from real-world practice settings. The proposed project will be based on Electronic Health Record (EHR) data obtained and collected in real time through the Practice Fusion healthcare platform. Pharma Co. X is seeking to learn more about intensity of chronic pain as measured by pain score and ERO use in real world settings. As assessment of pain is not routinely conducted in clinical practice this project will include a clinical decision support (CDS) program to message providers as to the importance of the routine assessment and documentation of level of pain and use of a pain management screening tool.

Practice Fusion's mission is to connect doctors, patients and data to drive better health and save lives. Founded in 2005, Practice Fusion pioneered an innovative free, web-based model for electronic healthcare record (EHR) technology. As the nation's largest and fastest-growing cloud based healthcare platform, Practice Fusion is a driving force in transforming US healthcare. Practice Fusion's real-time clinical EHR platform is also one of the largest clinical databases in the United States. One of Practice Fusion's main differentiators is our ability to intervene and message with both providers and their patients - before, during and after the patient visit enabling Practice Fusion to help implement and measure outcomes for multiple patient care interventions and programs.

Data in the Practice Fusion EHR database is updated daily and allows for the timely review of current prescribing and treatment practices in the United States. This Practice Fusion (PF) response presents an innovative solution leveraging PF's Clinical EHR Platform 'PF Platform' that connects doctors, patients and data. The PF Platform provides connectivity before, during, and after the patient visit. The proposed project will be based on existing Electronic Health Record (EHR) data obtained through the Practice Fusion EHR supplemented with data collected through data collection at the POC using the PF Platform.

Practice Fusion's response presents an innovative solution leveraging Practice Fusion's existing analytics platform, physician relationships and de-identified clinical patient level data via the Practice Fusion EHR Platform. PF will use our technology, existing and proven assets, and performance expertise to meet and/or exceed the scope and goal set forth in this proposal. We are confident in our abilities to meet or exceed your objectives and we look forward to partnering with you on this innovative project. We believe that by partnering with you on this project, together we will help fulfil the collective goals of Practice Fusion and Pharma Co. X

Objectives

The goal of this study is to gain better understanding of the current treatment landscape for extended-release opioids. Focus will be on intensity of pain as measured by pain score among patients with chronic pain. This will be accomplished by reviewing real-world practice data

leading up to new ERO prescription orders. Practice Fusion will evaluate the following objectives among patients receiving treatment with EROs for chronic pain:

Cross-Sectional Description of Treatment Landscape

1. Describe baseline patient and provider characteristics
2. Describe pain scores by treatment (type, duration, strength)

Longitudinal Description of Pain Scores

1. Describe treatment patterns for chronic pain therapy
    - Describe and evaluate initiation of long-acting agents
2. Describe and evaluate change in pain scores over time
    - 50% reduction in pain score

This will be done by leveraging information based on existing data obtained through the Practice Fusion EHR supplemented with data collected at the point of care (POC) as part of the implementation of a chronic pain CDS program.

Project Description

Practice Fusion proposes to conduct a retrospective database review on recent EHR data of chronic pain patients initiating an ERO (final definition to be determined based on discussion with Pharma Co. X). The study period of interest will be from January 1, 2013 through most recent data available in order to focus on the contemporary landscape of opioid therapy and uptake of newer products. Diagnosis, pharmacy, vital signs and pain score data is required to provide a full picture of the management of chronic pain patients.

The proposed study will involve two components:

1. Retrospective EHR data review
2. Clinical decision support (CDS) program

The cross-sectional component will describe current treatment patterns and the longitudinal component will provide descriptions of change over time in pain management as measured by pain scores. The longitudinal component will include a CDS program to enhance the collection of pain score assessments through the PF EHR Platform. The initial retrospective data review will inform the content and design of the CDS program component.

Data Source

Data for the proposed project will be drawn from the Practice Fusion EHR database. The Practice Fusion EHR database consists of data collected through the Practice Fusion cloud-based ambulatory EHR platform. The Practice Fusion ambulatory EHR platform is currently in use at over 13,000 practices in all 50 US states (Appendix A). A majority of Practice Fusion practices are single provider or small group practices. Data is available for over 25 Million unique patients starting in 2005, of which over 16 Million are currently active on the platform. Data is updated daily and is made available for analysis in a HIPAA-compliant de-identified research database on a weekly basis. A number of data validation and quality checks are performed as part of this process.

A comparison of the Practice Fusion ambulatory EHR database to information representative of the United States collected in the National Ambulatory Medical Care Survey (NAMCS) conducted by the Center for Disease Control (CDC), shows that Practice Fusion patients are similar in both demographic and clinical characteristics to utilizers of ambulatory healthcare in the United States (Appendix A).

The Practice Fusion EHR database includes information in the following domains:

- Patient demographics
  - Age, Gender, Race, Geographic region
- Patient characteristics
  - Weight, Height, BMI, Smoking status
- Provider characteristics
  - Physician specialty, Size of practice
- Office visits and chief complaints (symptoms)
- Diagnoses
- Prescriptions written and initial fill at pharmacy
- Other tests and procedures
- Pain scores (Limited availability)
- Other measurements

Methods

The overall project will have 3 components:

1. Retrospective EHR Data Analysis
   a. Cross-Sectional Description of Treatment Landscape
   b. Longitudinal Description of Pain Scores
2. Clinical Decision Support Messages
   a. Pain Assessment Documentation
   b. Follow-up Plan Documentation

3. Data Analysis and Evaluation of CDS Messaging

Retrospective EHR Data Analysis

Both the cross-sectional and longitudinal analyses will be made up from patients with a new prescription written for one of the study medications of interest. The cross-sectional component will consist of a 'snapshot' of data from the 6 month period leading up to the index prescription order. The longitudinal component will consist of a subset of these patients that have a minimum of 12 months of time in the database prior to the index prescription. The final set of patients as well as data elements to evaluate will be finalized based on discussion with Pharma Co. X

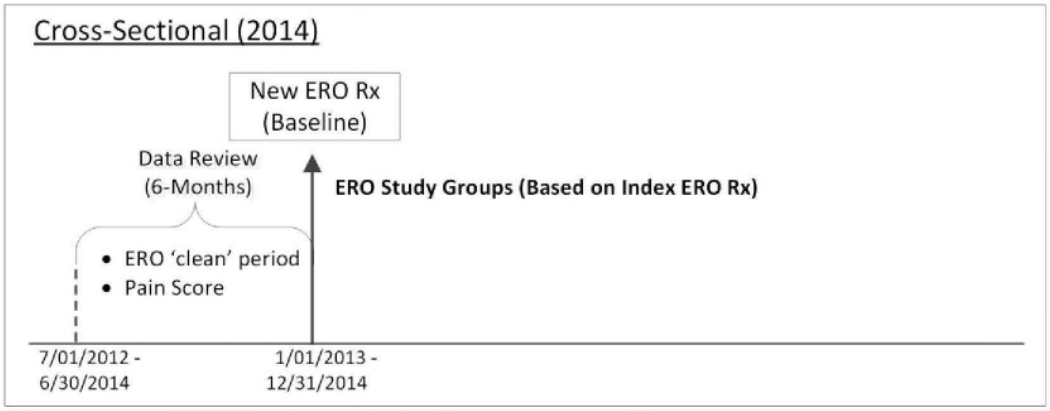
Patient Selection & Follow-up

The study population will be selected from patients meeting the study inclusion criteria based on a combination of treatment types, diagnosis codes and pain score measures (final criteria to be determined based on discussion with Pharma Co. X). Data will be reviewed for the time period January 1, 2013 to most recent available. Patients will be characterized by pain score and duration of treatment. Study groups will be defined based on treatment type. For the cross-sectional component data would be reviewed for the 6-month period prior to a recent new ERO prescription (Figure 1). For the longitudinal component an appropriate index date would be established (e.g., date of recent new ERO Rx) and patients would be followed for specified baseline pre-index and follow-up periods (e.g., 6-month baseline and 12 months follow-up) to explore project objectives (Figure 2). Study patients would be followed in the EHR database to evaluate project outcomes. Standard inclusion and exclusion criteria (e.g., current activity for the study duration, selected ages, treatments, and diagnoses) would be established with Pharma Co. X and implemented.

1. Cross-Sectional Description of Treatment Landscape

The cross-sectional component will be conducted first and will review new ERO prescription data for up to a two-year period of time.

FIGURE 1



Initial inclusion criteria:

1. Age 18+
2. New prescription for Study ERO, (January 1, 2013 – April 30, 2015)
3. 6-months prior Index ERO, time in database
4. Diagnosis of chronic pain
    a. Chronic pain (ICD9: 338.2)
    b. Type of pain (e.g. back pain, lumbar pain, osteoarthritis)
       AND
       Duration of pain diagnosis greater than 3 months (chronic pain)

Descriptive tables based on review of data in the 6-month period prior to the Index ERO prescription will be developed. Tables will include provider specialty and prescribing volumes, patient demographics and clinical profiles including prior medication(s) and pain diagnoses.

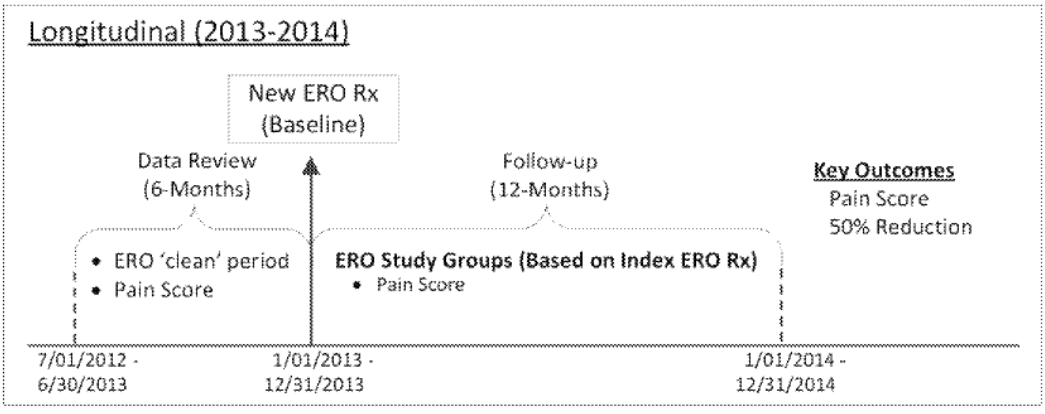
2. Longitudinal Description of Pain Scores

Following the cross-sectional component a longitudinal review of data will be conducted for those patients that have sufficient time in the database to evaluate outcomes (change in pain score) after the cross-sectional review period.

Initial inclusion criteria:

1. Age 18+
2. New prescription for Study ERO, (January 1, 2013 – December 31, 2014)
3. 6-months prior and 6-months post Index ERO, time in database
4. Diagnosis of chronic pain
    a. Chronic pain (ICD9: 338.2)
    b. Type of pain (e.g. back pain, lumbar pain, osteoarthritis)
       AND
       Duration of pain diagnosis greater than 3 months (chronic pain)

FIGURE 2



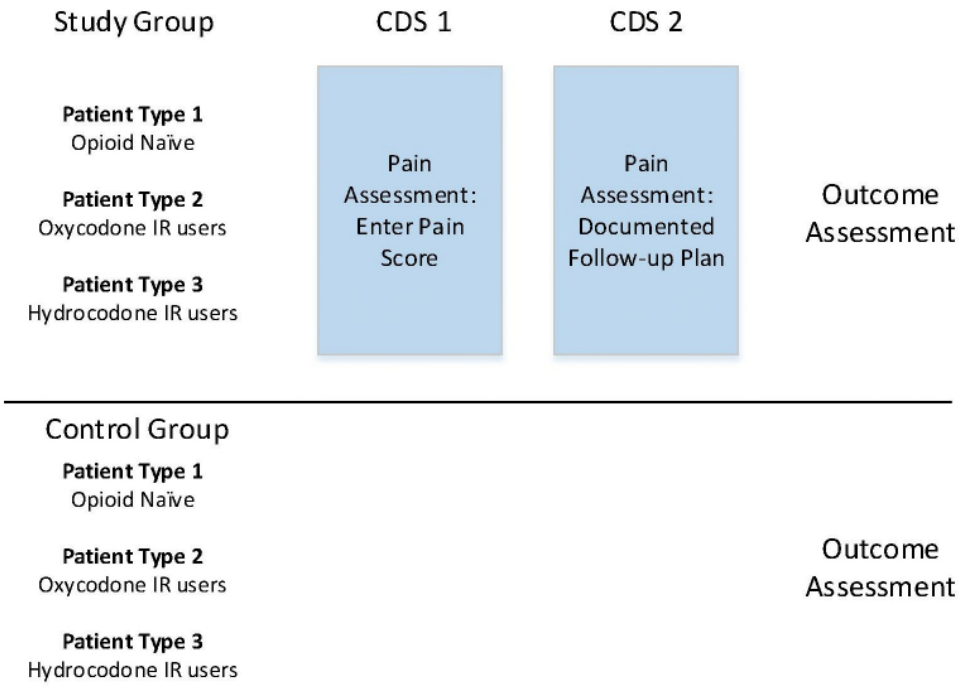
Clinical Decision Support (CDS) Program & Chronic Pain Assessment Education Campaign

The results of the retrospective component will be used to inform the sampling plan for this component of the study. Both the pain assessment CDS and the follow-up plan documentation CDS will be run for all providers/patients meeting program inclusion criteria. Practice Fusion will work with Pharma Co. X to develop the inclusion protocol and identify and/or design data collection instruments for data collection items. To drive provider use of the CDS program alerts a concurrent education awareness campaign will be run.

CDS Program Evaluation

The evaluation of this combined program will be from both a process perspective and an outcomes perspective. The process perspective will focus on traditional process type measures including impressions on the EHR Platform and amount of associated data entry while the outcomes perspective will focus on pain management outcomes and impact of pain and follow-up plan documentation on better pain management associated outcomes (Figure 3). What factors constitute better pain management will be developed and finalized based on discussion with Pharma Co. X

Figure 3: Evaluation Framework



Data Availability

Review of the Practice Fusion database for patients who have a new prescription written for an extended release (ER) opioid in the past 12 months shows approximately 10,000 patients are available for initial evaluation (Table 1). There are also sufficient counts of patients by product to allow for product specific reporting (Table 1). About 10 percent of patients have pain scores available in the period of interest, N= 835 (Table 2). This number will be sufficient to describe patients by level of pain but will not provide a large number of patients for analysis of change in pain score pre post ER opioid initiation.

TABLE 1 Patients with a New Rx for an Extended Release Opioid

Extended Release (ER) Opioids	Lookback time prior to Opioid Rx		
	>6m	>12m	>24m
Overall	**9,954**	**5,899**	**2,837**
Pharma Co. X	3,518	2,085	1,015
[redacted]	2,836	1,595	745
	1,774	1,149	610
	911	482	203
	764	465	235
	339	220	88
	259	172	79

TABLE 2 Patients with a New Rx for an Extended Release Opioid – with Pain Score

Extended Release (ER) Opioids	Lookback time prior to Opioid Rx		
	>6m	>12m	>24m
Overall	**835**	**554**	**320**
Pharma Co. X	344	232	131
	281	173	105
	119	84	48
[redacted]	79	54	32
	45	26	17
	26	20	14
	26	20	11

Data Elements & Specification of Study Measures

Descriptions will include top diagnoses in each group, providers in each group and details on treatment (e.g. dose, duration, strength) and treatment pattern (e.g. switching, combinations). Evaluation will focus on pain scores and other pain related information available in the electronic record. The study measures of interest are outlined below. These measures will be further developed and defined with Pharma Co. X during the development of the project analytic plan. A detailed list of measures and definitions including relevant diagnosis, procedure, and NDC codes would be submitted to Pharma Co. X for review and approval. To the extent feasible, standardized time frames, measures and units will be utilized. To evaluate and compare study groups, the following measures will be assessed for each study group:

1. Demographic characteristics
    a. Age
    b. Gender
    c. Geographic region
2. Provider characteristics
    a. Provider specialty
3. Opioid use & other pain therapy
    a. Type of treatment
    b. Date started treatment
    c. Length of time on treatment
    d. Strength of treatment
4. Chronic pain diagnosis (ICD9:)
    a. Diagnosis date
    b. Duration of diagnosis
5. Other pain diagnoses
    a. ICD9 code (selected types of pain)
    b. Diagnosis date
    c. Duration of diagnosis
6. Comorbidities

7. Pain scores
    a. Date
    b. Level (0-10)
8. Descriptors of pain
    a. Type of pain
    b. Location of pain
    c. Intensity of pain
    d. Other descriptors (from chart notes)

Existing extended release opioid (ERO) products on the market for consideration include:

- [redacted]
- Pharma Co. X
- [redacted]
- Pharma Co. X
- [redacted]
- [redacted]

Data Analysis

Data obtained from the PF EHR database will be imported into and maintained in a project analytic data file on which all data analyses would be performed. Tabulation of summary statistics, graphical presentations, and statistical analysis will be performed using statistical analysis tools (e.g., SAS, R). Demographics and baseline clinical characteristics of study patients including treatment will be described as counts and percentages for categorical variables and measures of central tendency (mean, median, standard deviation [SD], and min/max) for continuous variables (e.g., duration of therapy, laboratory values). P values will be calculated for selected key variables only, using the Chi-square test for categorical variables, Wilcoxon rank sum test or t-test for continuous variables depending on the distribution of data. Ninety-five percent confidence intervals will be calculated for key parameters. Statistical tests will be two-sided, with an α-level of 0.05 for statistical significance unless otherwise stated.

Tasks & Scope of Work by Study Component

Study Components

1. Study Initiation & Management
2. Retrospective EHR Data Review
3. CDS Programs
4. Assemble Data, Analysis & Reporting

Proposed project tasks and deliverables by study component in the order that they would be completed:

Component 1: Study Initiation & Management

Task 1: Project Initiation and Ongoing Project Management

At the outset of the project, members of the Pharma Co. X and Practice Fusion project teams will participate in an initial project kick-off meeting. The kick-off meeting will include discussion of project objectives and scope; project deliverables, timelines and milestones; and communication and meeting plan. During the course of the project, regular meetings will be held between the Pharma Co. X and Practice Fusion teams to review progress on the project and the project work plan. These meetings, which will be scheduled at project kick-off will ensure continued attention to project tasks and deliverables.

Component 2: Retrospective Data Review

Task 1: Analytic Plan

Following the kick-off meeting, Practice Fusion will prepare an Analytic Plan that describes the objectives of the project, the methodological approach, the project database, populations of interest, available sample sizes, outcomes to be evaluated, plans for data analysis, and table shells for presenting project findings. A draft of the analytic plan will be provided to Pharma Co. X for review and comment, after which it will be revised for final approval.

Task 2: Project Database

Practice Fusion will develop project-specific data files in support of the analytic plan. The project database or analytic data file will be created from source EHR data tables for patients meeting project inclusion criteria and maintained for the duration of the project.

Task 3: Retrospective Analysis

Analyses will be conducted by Practice Fusion according to the analytic plan. Preliminary findings and specified format including table shells will be prepared and provided to Pharma Co. X for review and comment.

Component 3: Clinical Decision Support Programs

Task 1: CDS Programs Protocol & Instruments

Practice Fusion will work with Pharma Co. X to develop the CDS protocol and identify and/or design data collection instruments for data collection items.

Task 2: Run CDS Programs

Patients eligible for each CDS program will be used to identify eligible providers. A set of providers will be randomly selected for receiving each CDS program and a set of providers will be selected as a control group to not receive each CDS program. Please refer to Appendix B for screen captures from the PF EHR.

Component 4: Assemble Data, Analysis & Reporting

Task 1: Overall Study Analysis Plan

Following the retrospective component of the project, Practice Fusion will prepare an Analytic Plan that describes the objectives of the Cross-Sectional Survey component, the methodological approach, the project database, populations of interest, available sample sizes, outcomes to be evaluated, plans for data analysis, and table shells for presenting project findings. A draft of the analytic plan will be provided to Pharma Co. X for review and comment, after which it will be revised for final approval.

Task 2: Study Database (4 quarterly updates)

The project database or analytic data file will be updated quarterly during the time period the CDS program is run from source EHR data tables for patients meeting project inclusion criteria and maintained for the duration of the project.

Task 3: Preliminary Analysis

Analyses will be conducted by Practice Fusion according to the analytic plan. Preliminary findings and specified format including table shells will be prepared and provided to Pharma Co. X for review and comment.

Task 4: Final Analysis & Study Report

Comments from Pharma Co. X will be reviewed and final data analyses will be completed. The final set of result tables will be prepared and submitted to Pharma Co. X along with a Project Report.

Terms | Project costs, terms, and payment schedule

The project will be initiated following formal written approval of this proposal by Pharma Co. X. The estimated timeframe and cost of data access and professional fees for this project are detailed below. This timeframe is based on an expected execution contract date of May 11, 2015. The estimated cost for the proposed project is $1,450,000 which includes professional fees associated with all aspects of conducting the proposed set of tasks, data collection and management, and data access and platform fees. Data dissemination including an abstract, poster content, and submission-ready manuscript content has an optional fee of $40,000.

Estimated Budget: Chronic Pain and CDS Support Program

Project Tasks and Description	Estimated Timeline	Investment
Study Initiation & Management		
TASK 1: Kickoff & Ongoing Project Management • *Project Kick-Off; Communications; Meetings*	ongoing	$25,500
TASK 2: Pre Protocol Considerations (inclusion criteria) • *Materials for CDS Program*	Week 1 - 6	$16,200
Study Initiation & Management Subtotal		**$41,700**
Retrospective Component		
TASK 1: Retrospective Component Analysis Plan • *Prepare Analytic Plan*	Week 2 - 6	$24,350
TASK 2: Create Project Database • *EHR Data*	Week 7 - 10	$27,620
TASK 3: Retrospective Analysis • *Conduct and Review Analyses with Client*	Week 11 - 14	$61,240
Retrospective Component Subtotal		**$113,210**
Prospective CDS Component (12 Months)		
TASK 1: CDS Protocol & Instruments • *Engineering for Platform CDS* • *Program Data Specifications & Instructions*	Month 2 - 4	$100,000
TASK 2: Provider Selection for CDS Program & Control Groups • *Conduct Selection*	Month 4	$5,000
TASK 3: Education Assessment Awareness Campaign (12 m) • *Awareness Campaign*	Month 5 -16	$150,000
TASK 4: Run CDS Programs (12 months) • *Data Collection*	Month 5 -16	$700,000
Prospective Component Subtotal		**$955,000**
Assemble Data, Analysis & Reporting		
TASK 1: Overall Study Analysis Plan • *Prepare Study Protocol*	Month 10	$22,500
TASK 2: Integrated Study Database (4 Quarterly updates) • *Initial Build* • *4 Quarterly Updates*	Month 5 -17	$58,300
TASK 3: Preliminary and Interim Analyses • *Review Preliminary Analyses with Client*	Month 18	$62,700
TASK 4: Final Analysis & Study Report • *Finalize Analyses & Report*	Month 19	$36,300
Assemble Data, Analysis & Reporting Subtotal		**$179,800**

Total Professional Fees	**$1,289,710**

Data Fee		
Practice Fusion EHR Data Access Fee • *Fee*		$125,000
Practice Fusion Data Fee Subtotal		**$125,000**
Total Practice Fusion Fees		**$1,414,710**
Optional - Data Dissemination		
Prepare abstract • Abstract and poster content	TBD	$10,000
Prepare manuscript • *Publication-ready content for initial submission*	TBD	$30,000
Data Dissemination Subtotal		**$40,000**
Total Study with Options		**$1,454,710**

Deliverables & Payment Schedule

The payment schedule outline below will be initiated following formal written approval of this proposal by Pharma Co. X. The full project fee will be invoiced upon completion.

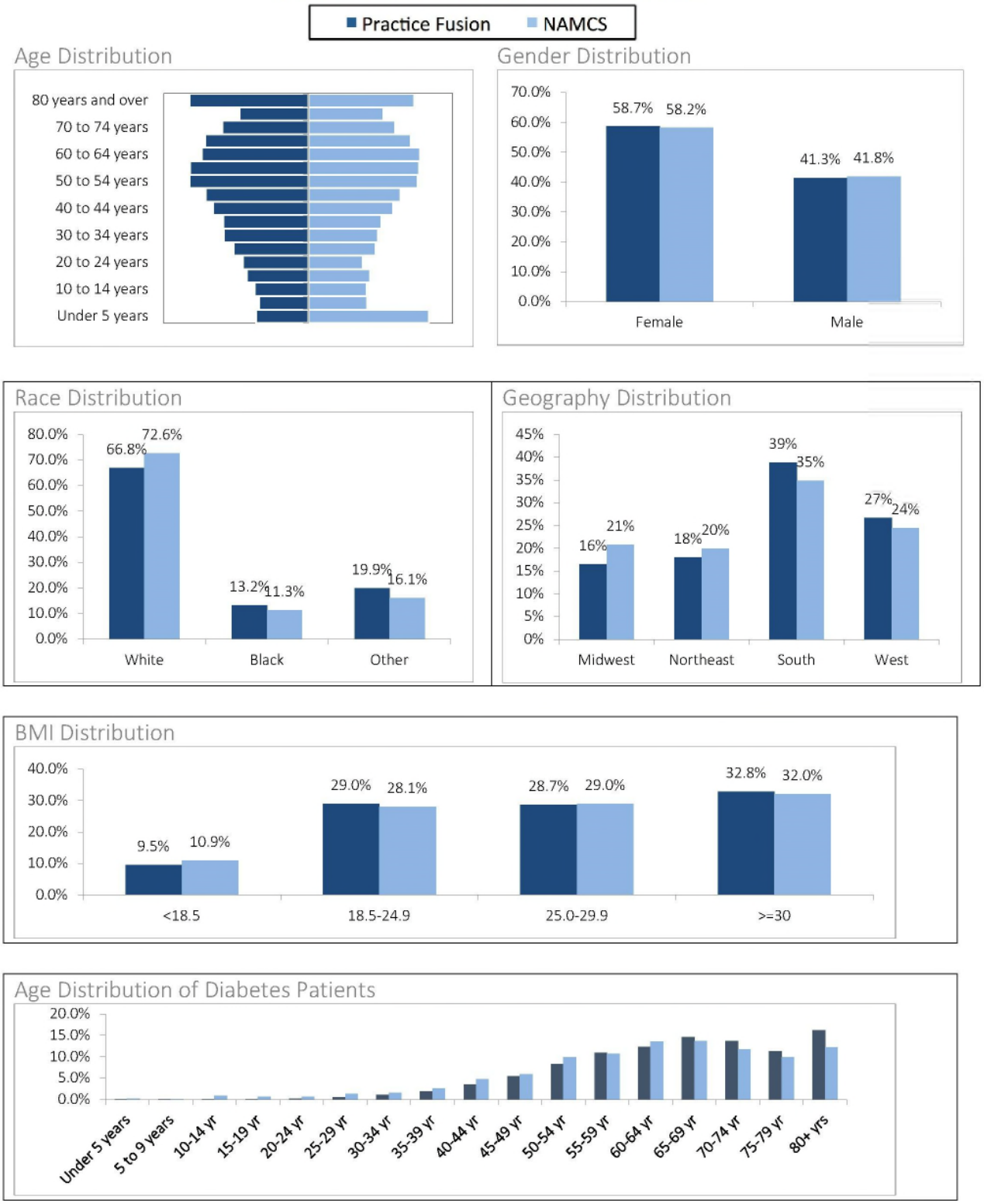
Deliverable Description	Invoice Timing	Invoice Amount
Retrospective Component, CDS Development and Delivery	Jun 2015	$550,000
Prospective Component, Custom Data Collection Analytics	Sept 2015	$250,000
Prospective Component, Data Assembly, Custom Data Collection Analytics	Dec 2015	$250,000
Prospective Component, Data Assembly, Custom Data Collection Analytics	Mar 2016	$250,000
Final Report	Jun 2016	$150,000

REFERENCES

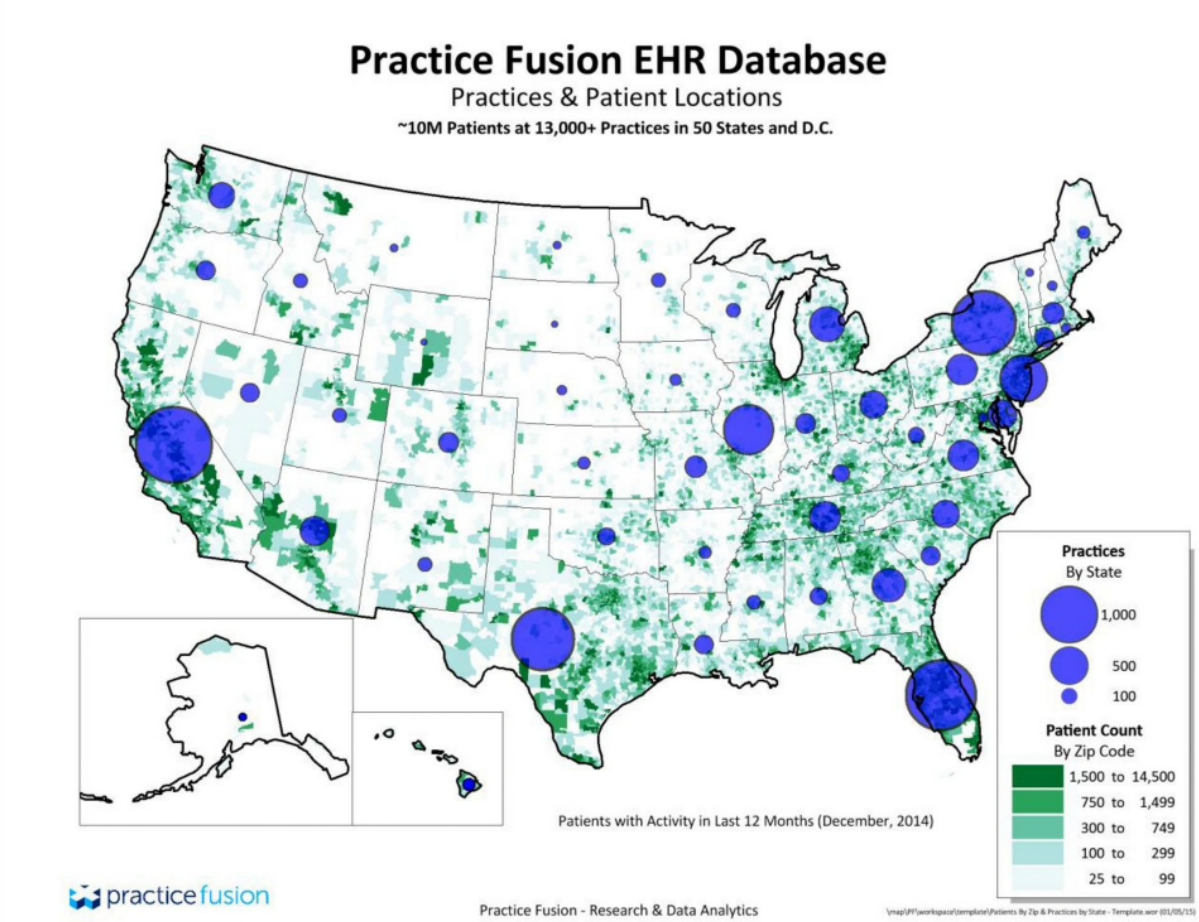
1. Vancouver style export from EndNote in rtf

APPENDIX A | Practice Fusion Dataset

Practice Fusion vs. NAMCS

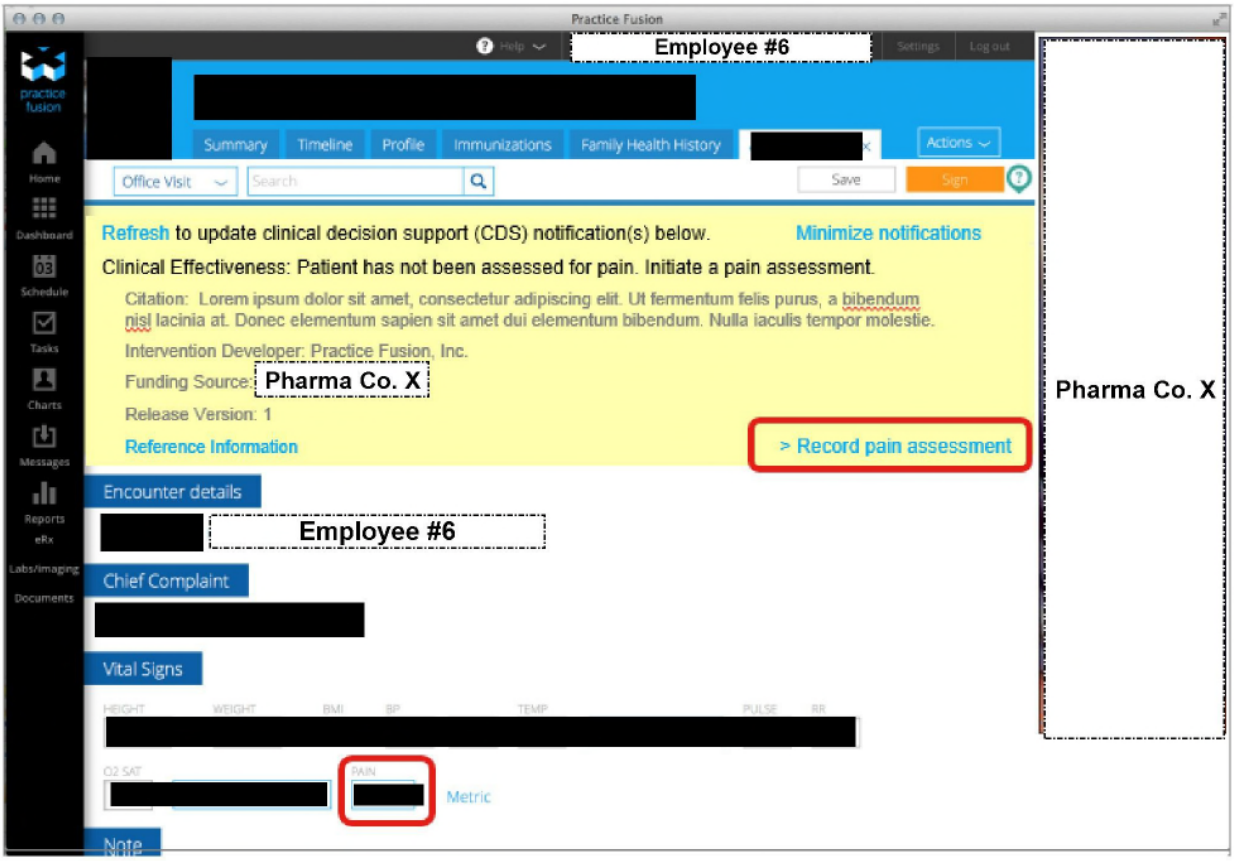


Location of Practice Fusion Practices

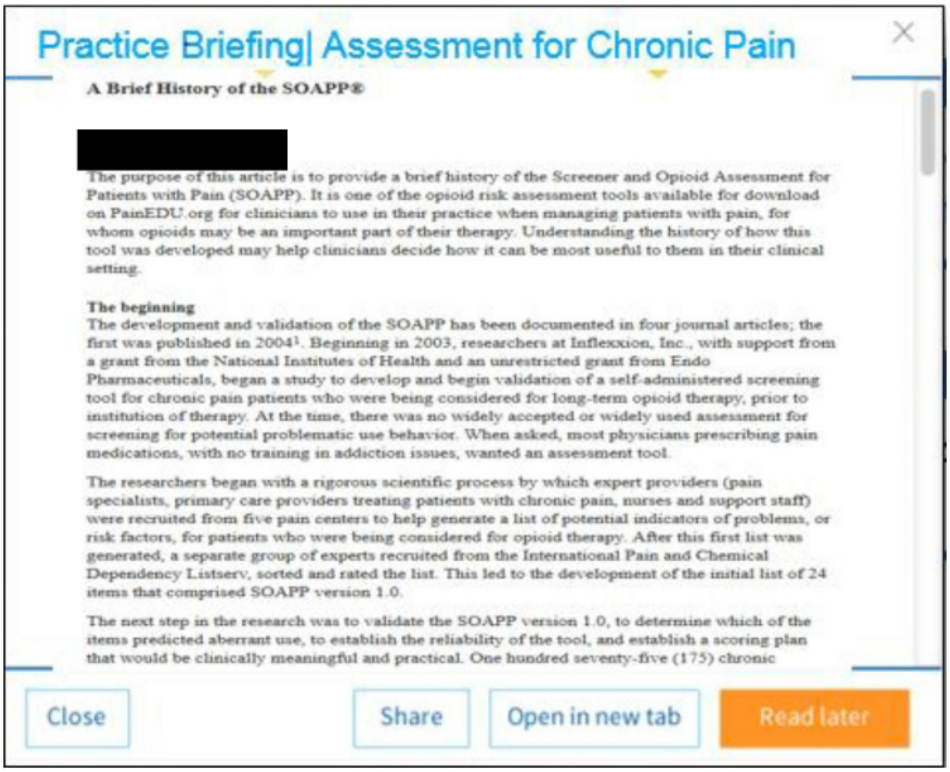


APPENDIX B: Screen shots from PF EHR Platform

CDS: Message Provider, Initiate a pain assessment



CDS: Practice Briefing, Assessment for Chronic Pain



Practice Briefing| Assessment for Chronic Pain

A Brief History of the SOAPP®

[redacted]

The purpose of this article is to provide a brief history of the Screener and Opioid Assessment for Patients with Pain (SOAPP). It is one of the opioid risk assessment tools available for download on PainEDU.org for clinicians to use in their practice when managing patients with pain, for whom opioids may be an important part of their therapy. Understanding the history of how this tool was developed may help clinicians decide how it can be most useful to them in their clinical setting.

The beginning

The development and validation of the SOAPP has been documented in four journal articles; the first was published in 2004[1]. Beginning in 2003, researchers at Inflexxion, Inc., with support from a grant from the National Institutes of Health and an unrestricted grant from Endo Pharmaceuticals, began a study to develop and begin validation of a self-administered screening tool for chronic pain patients who were being considered for long-term opioid therapy, prior to institution of therapy. At the time, there was no widely accepted or widely used assessment for screening for potential problematic use behavior. When asked, most physicians prescribing pain medications, with no training in addiction issues, wanted an assessment tool.

The researchers began with a rigorous scientific process by which expert providers (pain specialists, primary care providers treating patients with chronic pain, nurses and support staff) were recruited from five pain centers to help generate a list of potential indicators of problems, or risk factors, for patients who were being considered for opioid therapy. After this first list was generated, a separate group of experts recruited from the International Pain and Chemical Dependency Listserv, sorted and rated the list. This led to the development of the initial list of 24 items that comprised SOAPP version 1.0.

The next step in the research was to validate the SOAPP version 1.0, to determine which of the items predicted aberrant use, to establish the reliability of the tool, and establish a scoring plan that would be clinically meaningful and practical. One hundred seventy-five (175) chronic

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CDS: Document Assessment/Screener in Patient Chart